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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,264	09/10/1999	CYNTHIA C. MORTON	10286/008001	3961

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Supplemental Notice of Allowability	Application No. 09/394,264	Applicant(s) MORTON ET AL.	
	Examiner Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *March 10, 2005*.

2. ☒ The allowed claim(s) is/are *35-61 and 64-69*.

3. ☒ The drawings filed on *September 10, 1999* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

It appears that claims 35 and 43 contain a typographical error. The second part of the claims reads "..instructions for a diagnosing hearing disorder..." should read "...instructions for diagnosing a hearing disorder...."

The application has been amended as follows:

In claim 34, line 8: before 'diagnose' delete "a" and before 'hearing' insert -a-.

In claim 43, line 11: before 'diagnose' delete "a" and before 'hearing' insert -a-.

The following is an examiner's statement of reasons for allowance: SEQ ID NO 1 and 2 are found in application US 2002/0127584 A1 (see specifically SEQ ID NO: 227 and 228), however, the application does not provide any teaching of amplifying specific regions within the nucleic acid sequence. The application also does not teach that mutations associated with the sequences are associated with hearing loss. The application does not provide any teaching to point to the amino acid residues of proline at residue 51, valine at residue 66, glycine at residue 88 or tryptophan at residue 117 and their role in hearing loss. Thus the application of US 2002/0127584 A1 cannot serve as prior art when it does finally issue into a patent.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/16/05

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. –34. (Canceled)

35. (Currently amended) A kit for diagnosing a subject at risk for a hearing disorder, comprising: at least two nucleic acid primers which hybridize under stringent conditions to a nucleic acid sequence of SEQ ID NO: 1 or complement thereof, wherein the primers amplify all or a portion of exons 4 and 5 of SEQ ID NO:1 such that one or more nucleotides encoding one or more of an amino acid at residue 51, an amino acid at residue 66, an amino acid at residue 88 and an amino acid at residue 117 of SEQ ID NO:2 is amplified; and

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[[and]] instructions for ~~a~~ diagnosing a hearing disorder by detecting a substitution of one or more nucleotides encoding one or more of a proline at residue 51 of SEQ ID NO:2, a valine at residue 66 of SEQ ID NO:2, a glycine at residue 88 of SEQ ID NO:2, and a tryptophan at residue 117 of SEQ ID NO:2.

36. (Previously presented) The kit of claim 35, wherein the hearing disorder is DNFA9.

37. (Currently amended) The kit of claim 35, further comprising a nucleic acid probe which hybridizes under stringent conditions to the complement of SEQ ID NO:1, or [[or]] a nucleic acid sequence that differs from SEQ ID NO:1 at one or more nucleotides encoding one or more of a proline at residue 51 of SEQ ID NO:2, a valine at

residue 66 of SEQ ID NO:2, a glycine at residue 88 of SEQ ID NO:2, and a tryptophan at residue 117 of SEQ ID NO:2 and which detects the absence or presence of a substitution at one or more nucleic acids that encode the proline at residue 51 of SEQ ID NO:2, the valine at residue 66 of SEQ ID NO:2, the glycine at residue 88 of SEQ ID NO:2, or the tryptophan at residue 117 of SEQ ID NO:2.

38. (Previously presented) The kit of claim 37, wherein the kit comprises more than one probe.

39. (Previously presented) The kit of claim 37, wherein the probe is a labeled probe.

40. (Previously presented) The kit of claim 38, wherein one or more of the probes is a labeled probe.

41. (Previously presented) The kit of claim 37, wherein the primer is at least 12 nucleotides in length.

42. (Previously presented) The kit of claim 37, wherein the primer comprises at least 12 consecutive nucleotides of SEQ ID NO:1.

43. (Previously presented) A kit for diagnosing a subject at risk for a hearing disorder, comprising: one or more nucleic acid probes which hybridize under stringent conditions to the complement of SEQ ID NO:1 or a nucleic acid sequence that differs from the SEQ ID NO:1 at one or more nucleotides encoding one or more of a proline at residue 51 of SEQ ID NO:2, a valine at residue 66 of SEQ ID NO:2, a glycine at residue 88 of SEQ ID NO:2, and a tryptophan at residue 117 of SEQ ID NO:2 and which detects the absence or presence of a substitution at one or more nucleic acids that encode the

proline at residue 51 of SEQ ID NO:2, the valine at residue 66 of SEQ ID NO:2, the glycine at residue 88 of SEQ ID NO:2, or the tryptophan at residue 117 of SEQ ID NO:2; and

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[[and]] instructions for ~~a~~ diagnosing a hearing disorder by amplifying all or a portion of SEQ ID NO:1 such that one or more nucleotides encoding one or more of an amino acid at residue 51, an amino acid at residue 66, an amino acid at residue 88 and an amino acid at residue 117 of SEQ ID NO:2 is amplified and detecting the absence or presence of a substitution of one or more nucleotides encoding one or more of a proline at residue 51 of SEQ ID NO:2, a valine at residue 66 of SEQ ID NO:2, a glycine at residue 88 of SEQ ID NO:2, and a tryptophan at residue 117 of SEQ ID NO:2.

44. (Previously presented) The kit of claim 43, wherein the hearing disorder is DFNA9.

45. (Previously presented) The kit of claim 43, wherein the probe is a labeled probe.

46. (Previously presented) The kit of claim 43, wherein the kit comprises two or more probes and at least one of the probes is a labeled probe.

47. (Previously presented) The kit of claim 43, wherein the probe is at least 12 nucleotides in length.

48. (Previously presented) The kit of claim 43, wherein the probe comprises at least 12 consecutive nucleotides of SEQ ID NO:1.

49. (Previously presented) A nucleic acid primer for diagnosing a hearing disorder which hybridizes under stringent conditions to a portion of the nucleic acid

sequence of SEQ ID NO: 1 or complement thereof, wherein the primer amplifies all or a portion of exons 4 and 5 of SEQ ID NO:1 such that one or more nucleotides encoding one or more of an amino acid at residue 51, an amino acid at residue 66, an amino acid at residue 88 and an amino acid at residue 117 of SEQ ID NO:2 is amplified.

50. (Previously presented) The nucleic acid primer of claim 49, wherein the primer amplifies a portion of exon 4 that comprises nucleic acids encoding a proline at residue 51 of SEQ ID NO:2.

51. (Previously presented) The nucleic acid primer of claim 49, wherein the primer amplifies a portion of exon 4 that comprises nucleic acids encoding a valine at residue 66 of SEQ ID NO:2.

52. (Previously presented) The nucleic acid primer of claim 49, wherein the primer amplifies a portion of exon 5 that comprises nucleic acids encoding a glycine at residue 88 of SEQ ID NO:2.

53. (Previously presented) The nucleic acid primer of claim 49, wherein the primer amplifies a portion of exon 5 that comprises nucleic acids encoding a tryptophan at residue 117 of SEQ ID NO:2.

54. (Previously presented) The nucleic acid primer of claim 49, wherein the hearing disorder is DNFA9.

55. (Previously presented) The nucleic acid primer of claim 49, wherein the primer is at least 12 nucleotides in length.

56. (Previously presented) The nucleic acid primer of claim 49, wherein the primer comprises at least 12 consecutive nucleotides of SEQ ID NO:1.

57. (Previously presented) A nucleic acid probe for diagnosing a hearing disorder which hybridizes under stringent conditions to the complement of SEQ ID NO:1 or a nucleic acid sequence that differs from the SEQ ID NO:1 at one or more nucleotides encoding one or more of a proline at residue 51 of SEQ ID NO:2, a valine at residue 66 of SEQ ID NO:2, a glycine at residue 88 of SEQ ID NO:2, and a tryptophan at residue 117 of SEQ ID NO:2 and which detects the absence or presence of a substitution at one or more nucleic acids that encode the proline at residue 51 of SEQ ID NO:2, the valine at residue 66 of SEQ ID NO:2, the glycine at residue 88 of SEQ ID NO:2, or the tryptophan at residue 117 of SEQ ID NO:2.

58. (Previously resented) The nucleic acid probe of claim 57, wherein the probes hybridizes to a portion of the complement of SEQ ID NO:1 or the nucleic acid such that a lesion at one or more nucleic acids encoding a proline at residue 51 of SEQ ID NO:2 is detected.

59. (Previously presented) The nucleic acid probe of claim 57, wherein the probe is labeled.

60. (Previously presented) The nucleic acid probe of claim 57, wherein the hearing disorder is DFNA9.

61. (Previously presented) The nucleic acid probe of claim 58, wherein the probe detects a lesion at nucleotide 207 of SEQ ID NO:1.

62.-63. (Canceled)

64. (Currently amended) The nucleic acid probe of claim 57, wherein the [[probes]] probe hybridizes to a portion of the complement of SEQ ID NO:1 or the nucleic acid such that a lesion at one or more nucleic acids encoding a proline at residue 88 of SEQ ID NO:2 is detected.

65. (Previously presented) The nucleic acid probe of claim 64, wherein the probe detects a lesion at nucleotide 319 of SEQ ID NO:1.

66. (Currently amended) The nucleic acid probe of claim 57, wherein the [[probes]] probe hybridizes to a portion of the complement of SEQ ID NO:1 or the nucleic acid such that a lesion at one or more nucleic acids encoding a proline at residue 117 of SEQ ID NO:2 is detected.

67. (Previously presented) The nucleic acid probe of claim 66, wherein the probe detects a lesion at nucleotide 405 of SEQ ID NO:1.

68. (Previously presented) The nucleic acid probe of claim 57, wherein the probe is at least 12 nucleotides in length.

69. (Previously presented) The nucleic acid probe of claim 57, wherein the probe comprises at least 12 consecutive nucleotides of SEQ ID NO:1.